DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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To: The Medical Device Community

Last spring we announced plans to undertake an ambitious program of process improvement and reengineering within FDA's Center for Devices and Radiological Health (CDRH). I am pleased to present a combined first progress report on that program with an interim report on the Center's performance this fiscal year.

We have already initiated several pilot projects, and have more planned, that are designed to streamline our operations and be more responsive to our stakeholders. These changes will allow CDRH to re-channel our efforts to our most important work, so we can do it better and more efficiently. For example, we are now seeing dramatic improvements in review times for Premarket Approval (PMA) applications, building on similar, ongoing gains for Premarket Notification [510(k)] and Investigational Device Exemption (IDE) applications.

We are committed to continuing a results-oriented program that works with manufacturers and others in the medical device community, and hope you will continue to work with us to achieve our public health goals.

Sincerely yours,

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

NEW DIRECTIONS IN MEDICAL DEVICE REGULATION

AN FDA PROGRESS REPORT
AUGUST 1997

I. Introduction

CDRH:

How CDRH functions – FDA's Medical Device Program:

Reviews new devices

- ♦ works with manufacturers to develop devices that are independently evaluated for safety and effectiveness, and gotten to market promptly with labeling and advertising that accurately describe the expected performance and risks;

Monitors problems, and

- ♦ identifies problems with already-marketed devices and assists manufacturers in correcting them; and

Inspects quality systems

- ♦ assures that manufacturers have quality systems in place to produce well-designed, well-manufactured products.

How well has the Center been doing its job?

Program redirection and implementing SMDA 90 slowed reviews

In 1990 following well publicized device failures which caused deaths, blindness or disfigurement the device law was strengthened. The Safe Medical Devices Act of 1990 included a number of new provisions and required the Center to write additional regulations and to implement new programs. At the same time, as a result of intense internal FDA and Congressional review, the Center was charged to apply higher scientific standards in the review of new devices prior to marketing. Responding to this mandate, the Center placed stringency of review above timeliness. This sent a clear message to the medical device industry: firms were expected to produce higher quality data to support the marketing of new products.

A frankly painful three-year period ensued. Industry not only had to adjust to the more rigorous requirements, but to a review program that fell significantly behind expected work time frames. This led to an increasingly frustrating, and at times confrontational, relationship between the Center and the device industry.

High standards create tradeoffs

The United States' gold standard expectation of scientific data inherently carries a trade off. Developing and independently reviewing data on how to use new devices and on risks and benefits keeps bad products off the market; but it also takes time for good products. And so, today marketing approval in the U.S. often is not the first in the world. Many products are first sold in countries with minimal or nascent clinical data review systems.

Consumers have confidence in U.S. products

The products that reach the U.S. market give American consumers, physicians and third party payers better assurance they are well designed and well manufactured, accompanied by data showing they are safe and effective, and labeled to describe how and in whom to use them. Working with manufacturers throughout development and during review can both speed product availability and provide these important protections.

Resources and management changes have helped

The situation began to improve in 1994, when Congress supplemented the Center's resources allowing a 10% increase in staff, and when we began to see the effect of several management initiatives. Since that time, we have been able to turn the Center's performance around, dramatically shortening the time it takes to process applications for new devices while maintaining rigorous scientific standards. Gratifying as this turn around has been, we know it isn't enough for patients, taxpayers or the industry, and that we must continue to improve.

A two-step approach to improvement:

The Center is engaged in an intense effort to improve our efficiency and effectiveness in accomplishing the above goals. Essentially, we have used a two-step approach.

Efficiency has increased

The first step has been performance enhancement, or improving the efficiency with which we carry out existing tasks - reducing the time it takes to process applications to market new devices, for example. We have made significant strides in this area and will continue to do so in the future. Our progress to date is summarized in this report.

Process improvement and reengineering are keys to further progress

The second (and more difficult) step, now also underway, is process improvement and reengineering. Here we are going beyond simply streamlining existing tasks. Looking at the program through the eyes of our various stakeholders, we are asking ourselves where our efforts might be refocused to maximize our impact on public health. We are re-examining key facets of our program. This means challenging old assumptions and asking ourselves where fundamental changes in our approach might work better for manufacturers and yield equivalent (or better) public health protection at less cost to the taxpayer.

In performing this re-appraisal, we have committed ourselves to a risk-based approach to our work. We are selectively focusing our resources on high-risk, high-impact products. And, we are putting less emphasis on those areas posing lower risk to the public, where our direct involvement adds less value.

Motivation:

We are building a results oriented program

In light of the positive results we have achieved over the past few years, why are we continuing to do these things? First, we are strongly committed to the Administration's initiative to streamline government operations by making them more responsive to the public and less costly, and to the results-oriented management philosophy expressed in the Government Performance and Results Act (GPRA).

But beyond this commitment, there is the issue of sheer necessity. As new technologies flourish, we are likely to see an explosive growth in the complexity and number of new medical devices. The result? Even if we achieve greater efficiency in carrying out existing tasks - we will soon be overtaken by our increasing workload. We must seek not only to do our present job better, but to redefine that job.

II. Progress in Performance Enhancement

The past two years have seen dramatic improvements in the speed and efficiency with which we evaluate new medical devices before they are marketed. Here are some examples:

Premarket Approval Applications (PMAs):

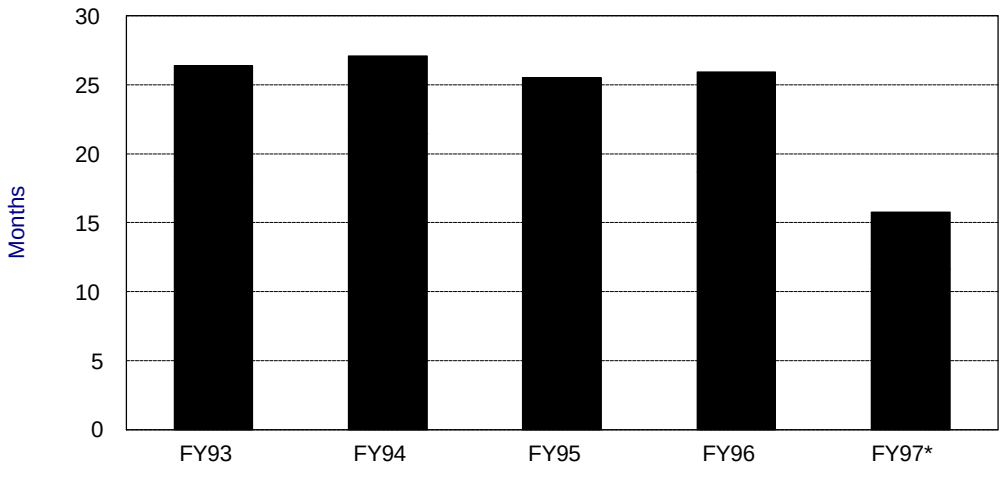
A Premarket Approval Application (PMA), represents the highest level of regulatory scrutiny applied to medical devices. A PMA is required for any new device that is not substantially equivalent to an existing one. The manufacturer submits complete scientific and clinical data on the device's safety and effectiveness. If FDA judges that the data establish the product is reasonably safe and effective, the PMA is approved.

More PMAs are being approved based on better data

In Fiscal Year 1996, we approved 43 PMAs, a six-year high. Of these approvals, 23 represented new technologies; this is twice the average number of new technology approvals over the past 15 years. This year we have already approved 36 PMAs. We anticipate, by the close of Fiscal Year 1997, about the same number of PMAs will be approved as last year. Among those already approved are such important new products for patients as the Vagus Nerve Stimulator for intractable epilepsy, the Deep Brain Stimulator for disabling tremors, and the Freehand assist device for quadriplegics.

The processing of PMAs is on track to be much faster than in past years; we anticipate reducing average total review time (including all cycles) by one-third or more, from approximately 26 months to 16 months or less.

PMA review times are faster



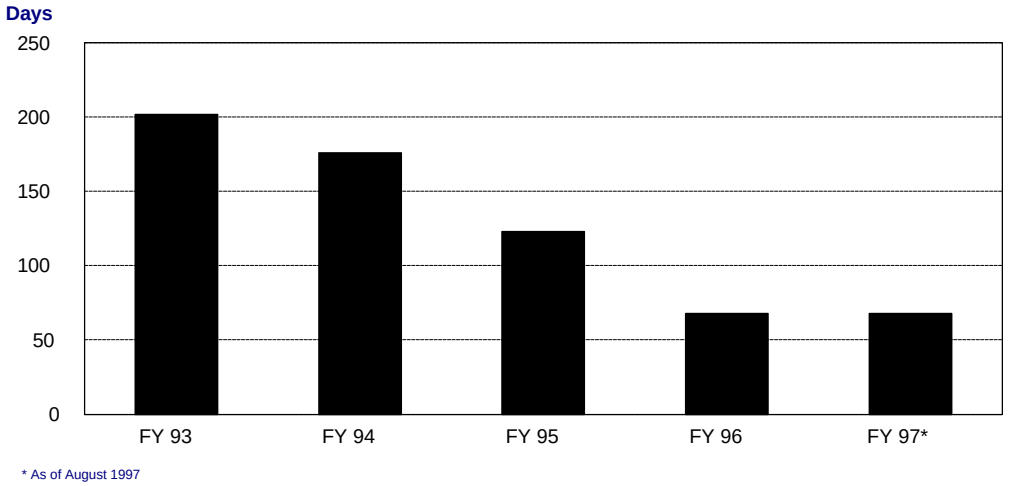
* As of August 1997

Investigational Device Exemptions (IDEs)

An Investigational Device Exemption (IDE) is required whenever a manufacturer wishes to test a new device on humans if the device may pose a significant risk. IDEs are the mechanism through which FDA assures that human subject protections are in place when manufacturers conduct clinical trials with a new device. The results of such clinical trials are often used to provide the data submitted in the PMA that establish the device's safety and effectiveness. FDA grants approval of the IDE after ascertaining that the study is well designed to elicit the desired information and that safety and ethical issues have been addressed.

In the past, FDA's evaluation of IDE submissions has often been very time consuming because manufacturers have not been familiar with FDA's expectations or requirements. This needed extensive correspondence on the part of both manufacturers and the agency. Worse still, sometimes this meant expensive mid-course corrections in clinical studies as manufacturers came to understand what needed to be done. We have recently worked more closely with device manufacturers on their IDE submissions. As a result, we have dramatically shortened the time until studies may begin.

IDE approvals are faster



Most IDEs are approved on first submission

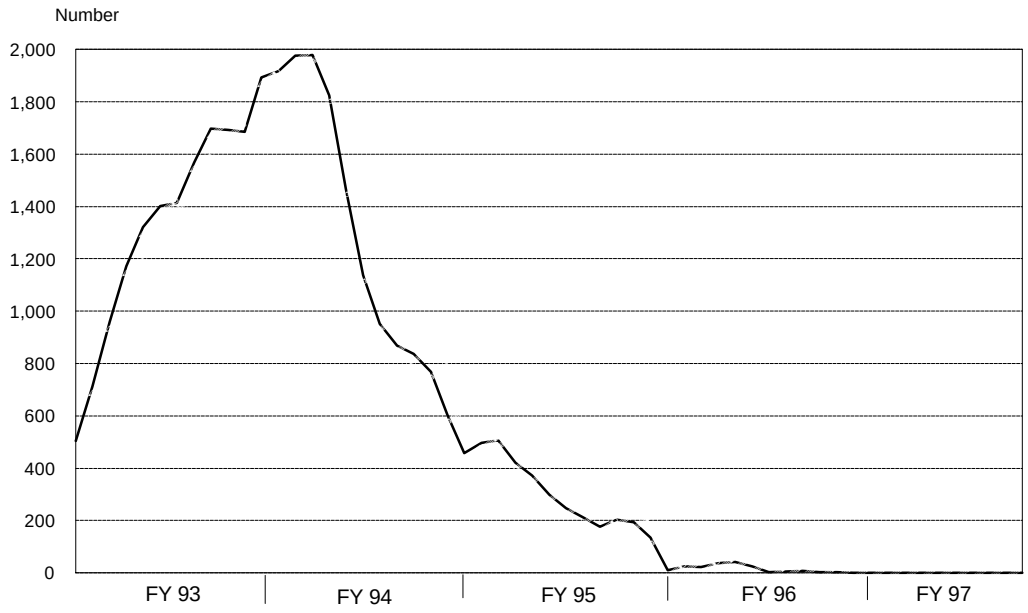
In Fiscal Year 1996, and so far in 1997, more than 70% were approved in their first 30-day cycle, the highest percentage since the inception of the IDE program.

Premarket Notifications (510(k)s)

Under section 510(k) of the law, more than 90% of devices are cleared for marketing when their manufacturer demonstrates they are substantially equivalent to an already-marketed device. To do this, the company submits to FDA a "premarket notification," generally referred to as a "510(k)," in which it justifies its claim for substantial equivalence.

Two years ago we succeeded in eliminating a massive backlog of 2,000 overdue 510(k)s.

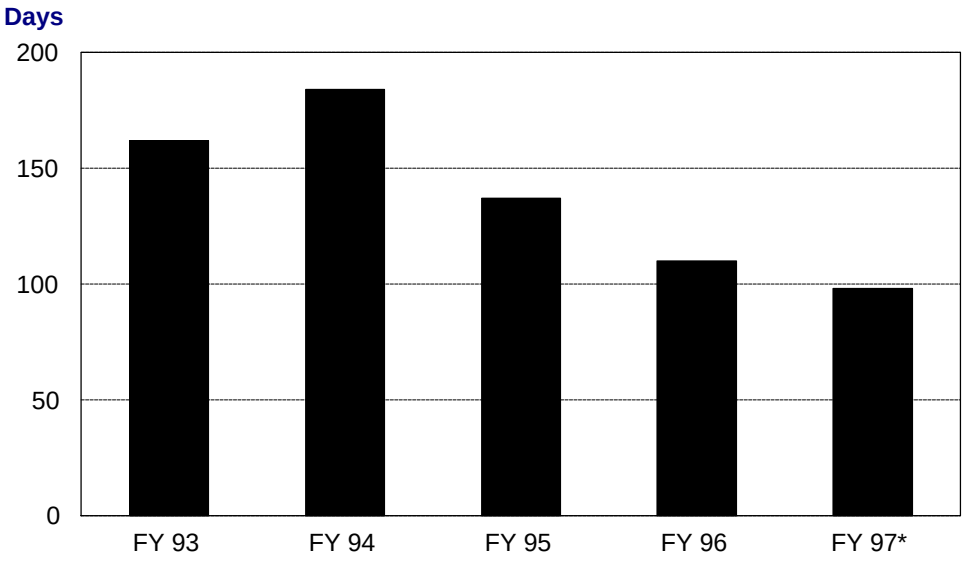
The 510(k) backlog is gone



Since then, we have not only prevented the buildup of a new backlog, but have made great strides in reducing the time it takes to process these submissions. So far in FY97, the average review time is 98 days, compared to a peak of 184 days in 1994.

510(k) Average Review Time

510(k) reviews are getting faster



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Improved communication with manufacturers

Not all of our performance enhancements have been as easily quantified as those described above. For example, we have made an intensive effort to improve communication with device manufacturers early in the development of devices and throughout the process of premarket submissions.

Reviewers interact more with sponsors

In this dialogue, which has occurred by telephone, by video conference, and in person, we have been helping manufacturers understand what we are looking for in their submissions. We explain what information will be needed, and why, and we resolve questions on the spot.

We have even begun sharing and discussing PMA deficiency letters before they are mailed so both the company and FDA are sure what we are asking for – and that we haven't overlooked information that has already been submitted. In addition to facilitating review of the present submission, such interaction and feedback increases the manufacturer's overall understanding of FDA's review process, so that submissions for future products should be improved as well.

Changes to our inspection program

Routine quality system inspections recognize manufacturers' needs

Last year we adopted a new approach to inspecting medical device manufacturers that includes three features:

- Routine inspections are preannounced and scheduled;
- Manufacturers' responses to observations made during an inspection are noted on the inspectional record; and
- When an inspection shows satisfactory quality systems are in place, FDA sends a letter documenting the satisfactory result.

This new program has been extremely well received by both the medical device industry and FDA field inspectors.

The future of performance enhancement

CDRH will do the most important work better

We recognize that despite the significant improvements described above, we can further enhance our timeliness and efficiency in our premarket review and other program areas, and we are committed to doing so.

Fundamentally, our commitment to change includes:

- A continued decrease in PMA review times through comprehensive, interactive reviews that encompass not just evaluating the application but also providing input during the product development phase.
- Improving communication to patients and practitioners through better product labeling.

- Developing more and better product standards in cooperation with the industry, so that standards-based clearance of 510(k)'d products can be used more effectively and extensively.

- Working through the list of pre-1976 class III products to either reclassify them or call for PMAs to establish safety and effectiveness.

- Enhancing our understanding of how devices are performing in the real world of clinical practice, so that we and the industry know when and how to inform users about potential problems.

- Selectively directing our inspection and enforcement activities toward relatively high-risk, high-impact devices, and enhancing industry's use of design controls, the cornerstone of the new Quality Systems regulations.

III. Progress in Process Improvement and Reengineering

In redesigning our processes, we consult with stakeholders

Through a period of intense "organizational introspection," we have been able to identify a number of possible changes in our program that might yield significant gains in efficiency without compromising our public health responsibilities. This introspection was not undertaken in a vacuum. We have actively sought the participation of the medical device industry, health professionals and consumers in re-thinking the basic elements of our program, and in devising ways of enhancing our efficiency and responsiveness. We want our program to reflect the needs of the outside groups affected by it. And so we have talked with these groups, enlisted them in focus-testing new ideas, and used their representatives as consultants to our reengineering teams.

We have 13 teams covering more than two-thirds of our activities working to improve and re-engineer the way the Center does it business.

Pilot tests:

New processes are pilot tested

As we identify areas needing process improvement, we are pilot-testing certain promising new approaches in carrying out our mission, and are considering additional pilot tests. These modifications to our program have been designed to be accomplished within the boundaries of existing legislation and with available resources. Here are a few examples among the many changes we are trying.

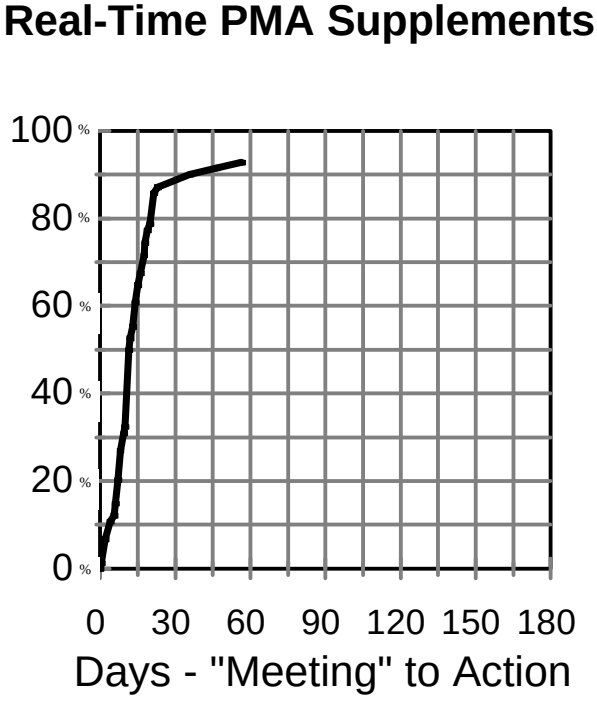
Current pilot tests:

"Real-time" review of PMA supplements:

When device manufacturers make significant changes in the way an already-marketed product is designed, manufactured or used, they must submit a Premarket Approval (PMA) supplement. The statute directs FDA to review these in 180 days. For certain less critical device changes, such as labeling or product design alterations, we have pilot-tested a system of "real-time" review, in which the changes are reviewed during a meeting, teleconference or videoconference with the firm.

Some PMA supplements can be reviewed in just a few days

This has already resulted in a dramatic reduction in review time (as little as five working days) and more efficient use of our staff. The original pilot test involved devices used in orthopedic, plastic, and reconstructive surgery. We are now expanding this to all premarket review branches and have used it 73 times since the pilot test began in April 1996.



Three real-time PMA supplements are still awaiting action, but most have been handled quickly. We expect that "real-time" review will be open to one half or more of the 500 PMA supplements we receive every year.

Periodic summaries of adverse event reports:

Expected MDR's can be reported in tables and submitted quarterly

Under our Medical Device Reporting (MDR) system, we have been requiring manufacturers to submit individual reports whenever one of their devices has been involved in a serious adverse event. These individual reports are essential when the adverse event is new or unforeseen, since they serve as a vital early-warning signal to FDA that an unexpected problem is surfacing. But when the adverse event is one that has been experienced many times in the past, or is referred to in the product's labeling, then the function of the report is simply to give FDA information about the frequency with which an expected event is occurring. For these kinds of events, individual reports may not be necessary or even helpful.

Accordingly, we are pilot testing a system in which manufacturers may use quarterly tabular summaries to submit information on adverse events that are well understood and anticipated. This should be far less time-consuming and expensive for both the manufacturer and FDA. Our long-term goal is to increase the number of lower-risk MDR reports that are summarized or entered automatically so we can redirect resources to problems that may pose a higher risk.

Decentralizing recall classification:

Most recall classifications can be done by FDA district offices

Recalls of medical devices initiated by FDA are classified by the agency according to potential public health risk. This classification has an important effect on the actions FDA and the manufacturer take in retrieving the product - in general, the greater the potential risk, the more rigorous the required corrective action. In the past, recall classification was performed at FDA headquarters after initial review and analysis in the field offices. This was time-consuming for the agency, and slowed feedback to the manufacturer sometimes delaying effective action.

We are now engaged in a four-month pilot test of a new system in which four of the FDA District Offices across the U.S. will be performing recall classification largely on their own about 90% of the time, based on precedents established through similar recalls in the past. This should get recall information to manufacturers more quickly and facilitate their taking appropriate action.

Inspections of contract sterilizing firms

Contract sterilizers don't need reinspection for every product

Manufacturers of sterile medical devices sometimes contract with other firms to perform the sterilization procedures. In the past, FDA would routinely inspect these contract sterilizing firms as a follow-up to inspecting the device manufacturer. Thus if the same sterilizing firm worked for several device manufacturers, it might be inspected several times in the same year.

To eliminate this "over-inspection" of sterilizing firms, we are pilot testing the use of a cross-check of previous inspections. This will help eliminate redundant FDA inspections, conserving resources for both the agency and the sterilizing firms.

Planned pilot tests

Changing the 510(k) paradigm:

Conformance to standards and design controls may allow abbreviated 510(k)'s

Because of the tremendous number of 510(k) submissions FDA receives each year, processing these documents has always been a particularly time-consuming task for the agency. As we have more national and international standards covering many aspects of devices and design controls, the value of FDA's review of all the data in 510(k)s is less.

To increase our efficiency without putting the public at risk, we have proposed changes in the process which will allow manufacturers of Class II devices whose design and manufacture conform to consensus standards to use an

abbreviated format for their 510(k) submissions. Similarly, we are exploring design controls as a possible substitute for case-by-case review when a manufacturer wishes to modify a design feature of a device.

More device categories can be exempted from 510(k)

Another problem with the existing 510(k) system is that many of the products for which 510(k)'s are submitted are of such low potential risk that even this minimal level of regulatory control may be unnecessary.

As a solution, we are proposing to exempt most Class I medical devices - those that pose little or no risk to users - from the 510(k) requirement (manufacturers will still be subject to facility inspections under FDA's Quality Systems regulations). Conversely, where de facto special controls exist, we are proposing to shift some Class I devices into Class II where they fit better under the statuatory scheme.

Product development protocols (PDPs):

Generic PDPs may fit well-understood class III devices

The present Premarket Approval Application (PMA) mechanism for approving new medical devices too often is a "hands-off" system. The manufacturer develops and submits data to establish a product's safety and effectiveness; but doesn't have a previous agreement with FDA about what data is expected. The agency then evaluates the data and decides whether it is sufficient. This makes the most sense for new products or emerging technologies where neither the manufacturer nor FDA can predict where the study results may lead but can be strengthened by more early interaction.

However, particularly for well-understood categories of products where the agency has received several similar PMAs, the system can be unnecessarily time-consuming for both the agency and the manufacturer: FDA must examine the data "de novo," expending resources to familiarize itself with the individual product, analyze the studies and identify possible inadequacies, and the manufacturer must re-submit information to correct for deficiencies.

Recognizing this, we are planning to pilot test the use of Product Development Protocols (PDPs) as an alternative to PMAs. Under this pilot test, FDA and the manufacturer will agree in advance on what will constitute good study design and a successful outcome. This means that when the study is completed, FDA need only check the results to see whether the previously agreed-upon criteria have been met. While this process is open to brand new types of devices, we are especially excited about its potential for products similar to several already developed. The PDP process should be quicker and more efficient than the PMA process, in that firms will not be making false starts on studies that may not be adequate. Two firms have already begun to pilot test PDPs.

Sentinel reporting system:

Looking closely at a sample of facilities may better profile adverse events

FDA's early-warning system for tracking adverse events with already-marketed devices has been the Medical Device Reporting (MDR) system. This requires that every hospital and nursing home report all serious incidents to the agency and/or the manufacturer. This system has several intrinsic problems: the huge volume of reports that FDA must amass and analyze, the basic reluctance of many medical facilities to file reports, and the erratic quality of many of these reports.

As an alternative to the MDR system, we are proposing to pilot-test a "sentinel" system. We will have a fixed sample of hospitals and other medical facilities across the nation report to us in depth about device problems. The resulting data would be extrapolated to reflect national trends. These sentinel facilities, carefully chosen to represent diverse geographical areas, size, specialties, etc., would be actively helped to submit complete and reliable information, which could be viewed "under a microscope."

IV. Conclusion

CDRH is and intends to stay a results oriented program that works with manufacturers to achieve our public health goals

As this report shows, we have made substantial progress in both of the goals we have set for ourselves. We have improved our performance in accomplishing today's tasks by getting our work done more quickly and effectively. In addition, we have to begin defining tomorrow's tasks in light of available resources and a burgeoning workload.

On a less tangible level, our "organizational culture" has shifted significantly as we have instituted changes and explored future options. Our people have been challenged to step back and re-appraise the meaning and importance of their work. They are meeting the challenge. They have shown a remarkable openness to new ways of doing things, and to the kind of constructive introspection about their jobs that can facilitate real change. As we make more alterations in the program, and as these bear fruit, this attitude of openness should strengthen. And that, in turn, should facilitate further change.

Our progress in performance enhancement has had a secondary benefit that goes beyond improved efficiency and timeliness. It has allowed us to re-direct resources, giving greater attention to products that have maximum impact on public health by using a risk-based approach. We are also focusing on methods to further increase our responsiveness to innovative new products.

In short, we think we are on the right track, and that we have the momentum to finish the job of re-inventing ourselves. But however we may change the content of our program, we will not change its fundamental goal. Our aim is to create a regulatory environment that facilitates bringing the benefits of scientific research to patients and health care practitioners as quickly as possible, while at the same time protecting them from unsafe or ineffective devices.